IMPLICATIONS OF ALTERNATIVE MEDICARE PAYMENT METHODS FOR PNEUMOCOCCAL VACCINATION

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IMPLICATIONS OF ALTERNATIVE MEDICARE PAYMENT METHODS FOR PNEUMOCOCCAL VACCINATION

EXECUTIVE SUMMARY

PURPOSE The purposes of this report are to (1) update the estimated level of use of pneumococcal vaccine in the United States, (2) examine factors that influence its use, and (3) assess how, if at all, selected alternative payment methods might affect the use of this vaccine.

FINDINGS CURRENT VACCINE USE

Based on data from the 1984 U.S. Immunization Survey (a household survey conducted for the federal government), about 3.5 percent of the entire U.S. population reported ever receiving pneumococcal vaccine and about 1.0 percent reported receiving it in the past twelve months (1984).

There are approximately 47 million Americans who are at higher than average risk of contracting pneumococcal infections. About 8.5 percent of the individuals in this population reportedly were immunized ever, and about 2.8 percent were probably immunized in 1984.

Approximately one-third of all pneumococcal vaccinations administered ever were given to persons aged 65 years or older.

FACTORS AFFECTING USE

Several factors affect the use of vaccines in general, e.g., vaccine availability; laws and regulations; characteristics of the target populations(s); characteristics of the vaccine; attitudes of patients and health care providers about their health, a given person's vulnerability to disease, and vaccine effectiveness or safety. Factors affecting the use of pneumococcal vaccine likely include physician awareness of and belief in the value of the vaccine, the public's knowledge about the vaccine, and methods used to deliver vaccines to adults. Some studies document a strong belief among physicians that the vaccine is safe and efficacious and that high risk patients can benefit from its use. These attitudinal findings, however, do not appear to have translated into actions, i.e., vaccination rates are quite low, even among high risk groups. Other studies have demonstrated impressively that special efforts to stimulate physicians' awareness of pneumococcal vaccine can lead to dramatic improvements in the vaccine's use.

The relationship between the level or type of payment for pneumococcal vaccination and its level of use is unclear. In general, vaccinations are low cost

services that are not likely to be relied upon by physicians or hospitals as "profit centers"; therefore, payment levels may not greatly influence vaccine use. Payment levels that do not cover physicians' or patients' vaccination costs, however, certainly could facilitate a low vaccine use rate.

IMPACT OF ALTERNATIVE PAYMENT PLANS

Although the impact of payment levels on vaccination rates is unknown, there are a few actions that the Health Care Financing Administration (HCFA) could take related to the use of this vaccine among Medicare beneficiaries.

First, under Modification/Refinements of the Current Medicare Payment Mechanisms, HCFA could:

(1) Survey carrier payment levels throughout the country to assess the relationship between physicians' and patients' vaccination costs and payment levels and, if deemed appropriate, encourage/require carriers to cover costs.

(2) Promote the use of pneumococcal vaccine among hospitalized Medicare beneficiaries to help reduce future hospitalization for pneumococcal infections. Such promotion could be through either education programs or financial incentives.

Second, HCFA could establish uniform relgional or a national fee schedule for pneumococcal vaccination,

similar to the schedules being developed by medicare for laboratory tests.

Third, HCFA could explore the economic and clinical implications of including pneumococcal vaccine in a package of preventive services offered to Medicare beneficiaries. Such a package will soon be offered through a Medicare demonstration project. The package currently includes influenza, but not pneumococcal, vaccine.

Fourth, in capitation programs, HCFA could evaluate the economic and clinical impacts of pneumococcal vaccinations by either financing a new demonstration project or by including such an investigation in currently approved fee-for-service demonstration projects (see above) and extrapolate results to capitation settings.

Alternatively, HCFA could promote the use of pneumococcal vaccine ini capitation programs through educational programs or possibly by initiating financial incentives for providers.

I. INTRODUCTION

In 1977, the U.S. Food and Drug Administration (FDA) approved for marketing a polysaccharide vaccine designed to prevent infectious diseases caused by 14 different types of pneumococci (a type of bacterium). The use of this vaccine is intended primarily to help reduce the incidence, morbidity, and mortality of pneumococcal pneumonia among individuals at a high risk of contracting this illness, e.g., those 65 years and older. In 1983, the FDA approved an expanded version of this vaccine that induces antibodies against 23 types of pneumococci.

In 1979, the Congressional Office of Technology Assessment (OTA) studied several aspects of pneumococcal vaccine, including its development, indications for use, safety, efficacy, cost-effectiveness, and reimbursement. [U.S. Congress, OTA, 1979]

Primarily based on information derived from OTA's study, the U.S. Congress enacted legislation that mandated the Health Care Financing Administration (HCFA) to include pneumococcal vaccination in the Medicare benefit package.

In 1984, OTA completed a subsequent re-evaluation of this vaccine and determined:

(1) The vaccine still appeared to be a relatively cost-effective preventive medical technology, although the net cost per year of healthy life gained varies substantially, given certain assumptions based on more recent data, and

(2) Based on vaccine sales data, at most 20 to 35 percent of the U.S. population at highest risk of con-

tracting pneumococcal disease has been vaccinated.

The purpose of this paper is to update the estimated level of use of this vaccine, examine the factors that influence its use, and assess how selected alternative payment methods might affect the use of this vaccine.

II. CURRENT LEVEL OF PNEUMOCOCCAL VACCINE USE

A. Results from the 1984 U.S. Immunization Survey

Measuring the nationwide level of use of pneumococcal vaccine has always been difficult, because until 1984, no governmental agency or private sector entity attempted this task. In its previous estimates, OTA used vaccine sales data as a proxy for vaccine use data. [U.S. Congress, OTA, 1984]

In its 1984 U.S. Immunization Survey, the Centers for Disease Control (CDC) attempted to estimate the number of persons who received pneumococcal vaccine. Data from this survey are displayed in Tables 1 and 2.

Table 1. Number and Percent of Total Persons and Persons With Conditions† Receiving Pneumococcal Pneumonia Vaccine Ever by Age, All Races Combined, United States, 1984

Age Group	Population (Thousands)	Percent Receiving Vaccine	Unknown	Number With Conditions† (Thousands)	Percent Receiving Vaccine	Unknown
1	3,648	1.8	5.8	—*	—*	—*
1-19	66,227	2.6	7.4	—*	—*	—*
20-29	41,595	2.4	7.8	2,397	4.4	4.7
30-39	36,100	2.0	6.8	3,352	6.0	4.3
40-49	24,960	2.6	7.6	4,122	5.1	4.2
50-64	32,933	4.3	7.5	10,485	8.3	3.3
65+	26,551	9.8	7.6	12,820	13.8	3.4
TOTAL	232,014	3.5	7.4	33,176	9.5	3.7

†These conditions include chronic illnesses, especially cardiovascular disease and chronic pulmonary disease, and splenic dysfunctions, asplenia, Hodgkin's Disease, multiple myeloma, cirrhosis, alcoholism, renal failure, crebrospinal fluid leaks, and conditions associated with immunosuppression.

*Not reported.

SOURCE: Unpublished data, "U.S. Immunization Survey, 1984" Centers for Disease Control, Division of Immunization, Atlanta, July 1985.

Table 2. Number and Percent of Total Persons and Persons With Conditions† Receiving Pneumococcal Pneumonia Vaccine Within Past Twelve Months, by Age, All Races Combined, United States, 1984

Age Group	Population (Thousands)	Percent Receiving Vaccine	Unknown	Number With Conditions† (Thousands)	Percent Receiving Vaccine	Unknown
1	3,648	1.0	4.6	—*	—*	—*
1-19	66,227	0.7	4.9	—*	—*	—*
20-29	41,595	0.4	4.5	2,397	1.1	0.7
30-39	36,100	0.3	4.1	3,352	1.4	1.1
40-49	24,960	0.5	5.1	4,122	1.5	1.0
50-64	32,933	1.3	5.2	10,485	2.7	1.1
65+	26,551	3.3	5.8	12,820	4.5	1.6
TOTAL	232,014	1.0	4.9	33,176	3.0	1.3

†These conditions include chronic illnesses, especially cardiovascular disease and chronic pulmonary disease, and splenic dysfunctions, asplenia, Hodgkin's Disease, multiple myeloma, cirrhosis, alcoholism, renal failure, crebrospinal fluid leaks, and conditions associated with immunosuppression.

*Not reported.

SOURCE: 1984 U.S. Immunization Survey, Centers for Disease Control.

According to these survey data, about 3.5 percent of the entire U.S. population reported having received pneumococcal vaccine ever (since 1978), and 1.0 percent reported having received the vaccine within the past twelve months.

According to this survey, about 46,900,000 persons are considered at high risk of contracting pneumococcal diseases. This figure includes 26.5 million persons over 65 years, with or without conditions, plus 20.3 million people age 64 and under, with conditions. An estimated 8.5 percent of this high risk population reported receiving pneumococcal vaccine ever, and 2.8 percent reported receiving the vaccine within the past

twelve months.

About 32 percent of all vaccinations ever administered were given to persons age 65 years and older. Of the 3.152 million doses given to persons with one or more conditions, nearly 56 percent were administered to persons 65 years or older with conditions.

Based on these numbers, about 8,120,000 doses have been administered ever, with 3,152,000 doses being administered to the high risk population. Likewise, in 1984, about 2,300,000 doses were administered to all persons, with 995,000 going to the high risk population. Again assuming these numbers are correct, approximately 28 percent of all doses reportedly administered ever to the general population were given in 1984. About 32 percent of the doses given ever to the high risk population were administered in 1984.

According to U.S. vaccine manufacturers' data, about 12,228,000 doses have been sold ever, and 1,175,000 doses were sold in 1984. (Note: These figures are net of returns.) (See Table 3.)

Table 3. Total Sales of Pneumococcal Vaccine, Net of Returns, 1979-84

Year	Number of Doses
1978	2,964,000
1979	1,565,605
1980	1,774,135
1981	2,283,240
1982	1,152,510
1983	1,313,105
1984	1,175,025
TOTAL	12,227,620

SOURCE: Unpublished data, Lederle Laboratories and Merck Sharpe & Dohme, January and February 1984, July 1985

The discrepancies between the number of doses sold and the number reportedly administered could be explained by one or more of the following situations:

(1) Some persons in the surveyed population may have confused pneumococcal vaccine with influenza vaccine. This situation could have resulted in an over-estimated number of doses "administered during the past twelve months" being reported in the 1984 U.S. Immunization Survey. Likewise, this confusion could account for underreporting in the "total doses reportedly administered ever" category.

(2) There could be a residual stock of up to 4,108,000 doses of pneumococcal vaccine in pharmacies, hospitals, clinics, and physician offices throughout the United States. This situation would account for the difference between total doses sold and reportedly administered ever.

(3) The reported 2.3 million doses administered in 1984 could represent some combination of the 1.175 million doses sold in 1984 and residual vaccine stocked in health care facilities (purchased prior to 1984).

(4) The discrepancies could partly result from some type of statistical reporting error, since pneumococcal vaccine was first included in the U.S. Immunization Survey in 1984.

Because this vaccine has an estimated five- to eight-year duration of effectiveness in most recipients, it is not likely that many vaccinees have received more than one dose. In one study, involving a six-year, well-organized program designed to promote

influenza and pneumococcal vaccinations to high risk outpatients at the University of Chicago, approximately two to three percent of vaccine recipients were immunized twice. [Ratner and Fedson, 1983]

Data in Table 3 illustrate that pneumococcal vaccine sales have fluctuated from year to year. Peaks in sales occurred in 1978 (the year of market introduction) and 1981 (the year Medicare began paying for pneumococcal immunizations). Also, in 1981, the Immunization Practices Advisory Committee (ACIP) issued a second, more supportive, recommendation regarding the use of pneumococcal vaccine. OTA did not study the exact causes for these fluctuations. One likely contributing factor, however, was the level and nature of manufacturers' promotional activities.

B. Size and Nature of Population at High Risk of Contracting Pneumococcal Diseases

Pneumococcal vaccine is indicated for use among persons with chronic illnesses, who are at a higher than average risk of contracting pneumococcal infection. The federal government, through its Immunization Practices Advisory Committee (ACIP), recently expanded its recommendations for pneumococcal vaccine use. In 1981, the ACIP recommended that the vaccine be given to persons older than two with splenic dysfunction, asplenia, or certain chronic illnesses associated with a greater risk of pneumococcal disease, e.g., chronic kidney disease, asthma, emphysema, tuberculosis, chronic bronchitis, or chronic heart condition such as heart attack rheumatic heart condition, high blood pressure, or hardening of the arteries. At that time, ACIP did not

recommend pneumococcal vaccinations for healthy, elderly persons.

In 1984, the ACIP advocated that pneumococcal vaccine be given to all persons aged two years and older with any of the following illnesses: cardiovascular disease, chronic pulmonary disease, splenic dysfunction, asplenia, Hodgkin's disease, multiple myeloma, cirrhosis, alcoholism, renal failure, cerebral spinal fluid (CSF) leaks, and conditions associated with immunosuppression. [Recommendation, ACIP, 1984] The ACIP also now recommends pneumococcal immunization for "older adults, especially those aged 65 and over, who are otherwise healthy."

Based on these recommendations, the CDC estimates that the total population at high risk for contracting pneumococcal diseases totaled 46,900,000 people in 1984. Approximately 43 percent (20,356,000) are individuals 64 years of age or younger with one or more "high risk" medical conditions. The remaining 57 percent (26,551,000) are persons aged 65 years or older, with or without conditions.

A factor that may expand the potential target population for this vaccine in the next year or so is the duration of its effectiveness. For most persons, one vaccination likely provides an estimated five- to eight-year protection against pneumococcal infection. Further, in individuals with compromised (faulty) immune systems, the duration of the vaccine's effectiveness may be three years or less. It is possible that some portion of these individuals will need to be revaccinated to remain protected, although such revaccination is not recommended at this time, because of notable adverse reactions. [ACIP, 1984]

Based upon the 1984 U.S. Immunization Survey, approximately 10 percent (2,655,000) of the total population 65 years and older reported being vaccinated ever and nearly 14 percent of the population 65 years and older who had one or more conditions (1,769,000) reported receiving the vaccine ever. About 3.3 percent (876,000) of the total population 65 years and older and 4.5 percent (576,900) of this population with one or more conditions reported being vaccinated within the past twelve months.

These numbers indicate that about one-third of all pneumococcal vaccinations administered ever among the 65 and older population were given in 1984. If correct, these figures indicate a notable increase in vaccination rates in 1984. It is highly likely, however, that the surveyed population remembered 1984 vaccinations better than those administered in previous years.

III. FACTORS AFFECTING PNEUMOCOCCAL VACCINE USE

A. Introduction

The Institute of Medicine (IOM) recently described and evaluated several factors that likely influence the utilization of new vaccines. [IOM] This assessment identified at least seven such interrelated factors:

- vaccine availability
- statutory interventions, e.g., school immunization requirements
- characteristics of the target population, e.g., access to health care, size, age, etc.
- vaccine characteristics that affect provider utilization, e.g., route of administration, cost, storage, vaccination procedure, etc.
- vaccine characteristics that affect patient acceptance, e.g., number of doses, cost, route of administration, etc.
- provider attitudes toward the vaccine, e.g., perceptions of safety, efficacy, liability, patient need, etc.
- target population attitudes toward the vaccine, e.g., likelihood of contracting the target illness, severity of illness, vaccine safety and efficacy, etc.

The IOM developed a model for predicting likely utilization rates for new vaccines based primarily on assessments of lay and provider attitudes.

Based on a comprehensive review of previous studies, IOM concluded that the lay public's vaccine-seeking behavior can be predicted based on the health belief model. This model has five key elements which determine the degree to which a person seeks preventive health actions, including vaccinations, i.e.

1. perception of their susceptibility to the target illness,
2. perception of probable severity of that illness once contracted,
3. perceived benefits to be derived from an advocated action (e.g., being vaccinated),
4. perceived barriers to taking an advocated action (e.g., side effects of vaccine, cost, access, etc.), and
5. the occurrence of one or more cues to action to stimulate awareness of either illness threat or value of the advocated action.

The fifth element was studied by Kegeles in 1969. He conducted a study among black women in a medium-sized metropolitan area to test the effect of a comprehensive program designed to induce women to seek testing for cervical cancer. Specifically, he sought answers to these two questions: [Kegeles]

1. What relationship is there between beliefs and behavior?
2. What relationship would there be between beliefs and behavior as a result of different communications?

This program included a 3.5 minute interview during which experimental subjects were informed about the dangers of cervical cancer and the value of braining a screening test, i.e., early detection leads to a more favorable prognosis. Control subjects

were informed about iron deficiency and were given information describing cervical cancer testing (identical to that given the experimental subjects). All financial and logistical barriers to seeking such a test were removed, e.g., maps to the clinic, taxis, and babysitters were offered to all subjects.

Sixty-four percent of all subjects either made appointments or accepted free taxi rides to obtain the test, and 51 percent of these subjects (35 percent of the total) actually went to the clinic for testing.

An equal number of subjects in both groups either made appointments or accepted a free taxi voucher; however, 45 percent of the experimental subjects actually went to the clinic for testing, whereas only 22 percent of the control subjects did so.

Kegeles found no correlation between strong pre-intervention beliefs in either vulnerability to cervical cancer or effectiveness of the csreening test and test-seeking behavior. Following the intervention, i.e., the educational interview, however, more subjects who perceived themselves vulnerable and who believed the test was an effective action did seek the screening test than did those subjects who perceived themselves less vulnerable and who did not believe the test was effective. A strong belief in the test's effectiveness by itself did not correlate well with test-seeking behavior. Kegeles concluded the educational intervention probably "cued" test-seeking behavior among those subjects with previous strong beliefs rather than actually changing beliefs about vulnerability to cervical cancer and effec-

tiveness of the screening test.

IOM found that provider acceptance (and hence use) of new medical technologies, including vaccines, is also influenced by several factors, e.g.:

- Degree to which "opinion leaders" within the relevant medical community adopt the technology.
- Characteristics of the new technology, e.g., relative advantage over preceding or existing interventions; compatability with existing values, procedures, and past experiences; complexity of use; suitability for pilot studies; observability of results; and risk to the provider and the patient.
- Characteristics of the setting in which the new technology is to be used, e.g., attitudes, beliefs, structure of health care delivery system, etc.

Riddiough et al. [1981, p. 534] list several factors that may influence physicians' vaccine-prescribing behavior and that seem to fit within one or more of the innovation characteristics described above:

- attitudes and knowledge about the targeted disease
- attitudes and knowledge about the safety and efficacy of vaccines
- perceptions about a patient's need for vaccination
- consideration of revenue generated by administering vaccines
- consideration of the potential liability for vaccine-related injury.

The authors suggest that concern about possible adverse reactions and concomitant legal actions are the greatest obstacles to physician acceptance. They add that:

> in assessing a patient's need for a particular vaccine, physicians may consider (a) the likelihood of the patient's being exposed to a given disease-producing organism; (b) the patient's vulnerability to the disease after being exposed to the organism; and (c) the extent to which contracting the disease will disrupt the patient's life. [Riddiough et al., 1981:534]

This section will examine the potential impact of the following factors on the use of pneumococcal vaccine:

(1) Perceived vaccine safety and effectiveness by physicians, patients, and governmental public health agencies.

(2) Economic considerations, including vaccine price, cost effectiveness, and existing reimbursement policies.

(3) Physicians' and consumers' perceived value of preventing versus treating pneumococcal disease.

(4) Active methods of promoting pneumococcal vaccine use.

The next section of this report will address the implications of new payment methods on the use of pneumococcal vaccine.

B. Perceived Safety and Efficacy of Pneumococcal Vaccine

1. Physicians' Perceptions

Physicians have received somewhat conflicting information

concerning the clinical efficacy of pneumococcal vaccine. Although several reported studies demonstrated the vaccine's ability to induce protective antibodies [Schwartz, Shapiro, Hilleman, ACIP], some studies estimate the 14-valent vaccine's clinical efficiacy to be lower than originally projected, especially among elderly and immunocompromised populations. [Broome, Fraser, Bentley, Schwartz] At present, the 14-valent vaccine appears to have an overall efficacy rate of 60 to 80 percent, although this rate may be lower among patients with cirrhosis or renal failure. Based on limited data, the efficacy rate of the 23-valent vaccine may be close to 80 percent in preventing bacteremic pneumococcal disease. [Austrian; Robbins; U.S. Congress, OTA, 1984]

Although the impacts of these varying efficacy rates on physicians' use of the vaccine have not been measured, it can be assumed that such a factor could have constrained some physicians' use of this preventive technology. Some medical journal articles indeed cite a lack of clinical trial data, especially among patient populations for whom the vaccine is most likely to be beneficial, as a major reason for physicians' apparent lack of enthusiasm for the vaccine to date. [Fraser, Hirschmann] Because such trials require large patient populations, are expensive, and may be fraught with ethical concerns, however, they are not frequently undertaken. [Fedson (1985), Austrian, Clemens] One such study is currently being conducted by the Veterans Administration in an older, high risk population. Results should be released later in 1985 or 1986.

In spite of changing estimates of the vaccine's efficacy

being cited over the past few years, there is some evidence that physicians generally believe the vaccine works. In a recent study of generalist physicians, about 85 percent reported they believed the efficacy of the vaccine had been proven in clinical trials. [Berk] An earlier investigation yielded similar results. [Patriarca] Further, the 1985 Guide for Adult Immunization, published by the American College of Physicians, favorably discusses the vaccine's efficacy. This publication is not designed to promote the use of pneumococcal vaccine; rather, it represents an effort by a well-respected group of clinicians to disseminate objective information concerning adult immunization to practicing physicians. The information in this publication closely parallels the recommendations of CDC's ACIP concerning the use of pneumococcal vaccine. Inclusion of such information in the Guide represents a form of acceptance of the vaccine's efficacy by at least one element of the medical community.

Pneumococcal vaccine has been reported to be remarkably safe [Schwartz]; thus, safety should not restrict physicians from recommending its use. Because of the increased liability and notoriety surrounding adverse reactions caused by other vaccines, e.g., pertussio, physicians may be increasingly sensitive to potential adverse reactions from all vaccines. The CDC's ACIP reports that fever, myalgias, and severe local reactions have been reported in less than one percent of those given pneumococcal vaccine. Severe adverse effects, such as anaphylactoid reactions, have rarely been reported--about five per million doses administered. [Recommendation, ACIP, 1984]

2. Patients' Perceptions

There have been no studies to date that assess patients' perception of the safety and efficacy of pneumococcal vaccine.

The importance of patients' perceptions about and experiences with vaccine side effects, however, was demonstrated by Buchner and coworkers in a study involving influenza vaccine. [Buchner]. Concern, or lack thereof, about vaccine side effects was the primary factor in determining whether study subjects chose to be vaccinated or not over a two-year study period.

Only 11 percent of those patients who continually received influenza vaccine (over two years) reported previous side effects, while 60 percent of those not continuing to be vaccinated reportedly encountered side effects. Buchner also found a consistently positive correlation between patients' concern about influenza and their shot-taking behavior, i.e., those concerned were more likely to be vaccinated.

3. Governmental Public Health Agencies' Perceptions

Since the federal government's ACIP issues recommendations concerning the use of all vaccines, this committee's perception of a vaccine's safety and efficacy likely influences a vaccine's use. Until 1984, the ACIP had endorsed the use of pneumococcal vaccine for a somewhat limited targeted population, i.e., those persons with selected chronic illnesses who were at higher than average risk of contracting pneumococcal diseases. One factor influencing this cautious recommendation was the partially conflicting information regarding the vaccine's ability to produce protective

levels of antibodies, especially among immunocompromised patients.

In 1984 the ACIP broadened its suggested target population and recommended that the vaccine be administered to all "high risk" adults, i.e., individuals with certain illnesses who have an above average chance of contracting pneumococcal illnesses, and all persons 65 years or older who are otherwise healthy.

ACIP's updated recommendations have been cited in the medical literature [Fedson (1985), ACIP (1984)]. No studies have been conducted specifically to assess the impact of such literature on physicians prescribing and administering the vaccine.

C. Economic Considerations, Including Vaccination Cost, Cost-Effectiveness, and Existing Reimbursement Policies

1. Vaccination Cost

The Office of Technology Assessment (OTA) estimated the average cost of pneumococcal vaccination in the private sector to be $14.65 (in 1983 dollars). [U.S. Congress, OTA, 1984] This cost includes $4.43 for a dose of the vaccine and $10.22 for the physician's injection fee. If pneumococcal vaccinations were to be administered in a public immunization program, OTA estimated the hypothetical cost would be $3.80 in 1983 dollars.

In 1985, manufacturers' list selling prices for this vaccine range between $5 and $7 per dose. Pharmacies can add a 10 percent handling charge to this price for delivering vaccine to office-based physicians.

To date, no studies have been conducted to assess the impact, if any, of the vaccine's cost on its level of use. Cost to the

consumer (patient) should not be a major factor in demand for the vaccine among persons aged 65 and older, since Medicare pays for 100 percent of vaccination costs. As discussed below, however, the relationship between cost and Medicare's reimbursement level for this vaccine could influence physicians' decisions to use the vaccine.

Cost could enter this decision in two ways. First, if the carrier's "reasonable charge" level is notably below a physician's cost, that physician would have an economic disincentive to vaccinate. As stated by Dr. John Ball, American College of Physicians, "Reasonable payment for the service might help [improve the vaccine's use], but minimally, certainly, payment that does not cover costs is no positive incentive." [Ball] Second, if the carrier's payment level is notably below a physician's billed charge level, and that physician does not accept mandatory assignment, then the patient would be charged a notable copayment, which could discourage the vaccine's use.

2. Cost-effectiveness of Pneumococcal Vaccination

OTA studied the cost-effectiveness of pneumococcal vaccination in 1979 and updated its analysis in 1984 [U.S. Congress, OTA, 1984]

In its 1979 base case analysis, using either 1978 or 1983 dollars, OTA calculated that pneumococcal vaccination was slightly cost-saving for society, i.e., it generated a small savings when compared to the treatment of pneumococcal pneumonia for vaccinees aged 65 or older. Some assumptions used in this analysis include

these: 15 percent of all pneumonia cases are caused by pneumococci; 75 percent of pneumococcal pneumonia is caused by the types of pneumococci in the (14-valent) vaccine, the vaccine is 80 percent efficacious, and the duration of immunity is eight years. When OTA used a lower value for three variables, i.e., percent of pneumonia caused by pneumococci (10 percent), duration of immunity (3 years), and a combination of both these variables, the cost of gaining a year of healthy life for persons 65 or older rose to $1,300, $3,000, and $6,000, respectively. When 1983 vaccination and treatment costs were used, the net cost of gaining a year of healthy life ranged from cost saving to $6,154.

OTA also calculated the costs and benefits of pneumococcal vaccination to the Medicare program. Again using estimated 1983 treatment and vaccination costs, OTA calculated that Medicare's cost for generating a year of healthy life among its vaccinated beneficiaries ranged from $0 (cost saving) to $8,345, depending on the assumptions and variables considered.

OTA stated, "If 25 percent of elderly Medicare beneficiaries received pneumococcal vaccination (about 6.6 million people), the net cost to the Medicare program over time in 1983 dollars would be $37 million to $69 million to gain about 8,400 years of healthy life." [U.S. Congress, OTA, 1984]

Results of the 1978 OTA cost-effectiveness study were published in the New England Journal of Medicine [Willems]. The results of the 1984 updated study have not yet been published in the medical literature. The results of at least one of these

studies have been cited subsequently in several articles in the medical literature concerning pneumococcal vaccine. [Siebers, Klein (1983), Fedson] The degree to which data from these cost-effectiveness analyses influence physicians' prescription or administration of this vaccine is unknown. Further, as discussed below, the impact of these data on health care administrators', employers', and health insurance companies' decision to include this vaccine in their benefits packages is not known.

3. Existing Reimbursement Policies

As of July 1981, Medicare began paying for pneumococcal vaccination under Part B. This benefit is excluded from deductible and coinsurance requirements. Since it is a Part B benefit, the vaccine is also excluded from Medicare's diagnosis related groups (DRG)-based hospital payment program, which allows hospitals to bill Medicare separately for pneumococcal vaccinations administered to hospitalized beneficiaries. [U.S. Congress, OTA, 1984]

Medicare carriers are responsible for developing their payment level and procedures to reimburse physicians and hospitals for administering pneumococcal vaccine. At present, reimbursement levels can vary from carrier to carrier. This variation among four recently surveyed Medicare carriers, for example, ranged from $7.00 to $11.10. In all cases, payment is intended to cover both the vaccine's purchase price and the physician's or hospital's administration services. The carrier who pays $7.00 allows $5.00 for a dose of purchased vaccine and a $2.00 injection fee. The cost of the vaccine to physicians in that carrier's geographical

region, however, can range from about $5.50 to $7.50 per dose for vaccine purchased through normal distribution channels, i.e., manufacturer to community pharmacy to office-based physician. [Yee] Hence, that carrier's reimbursement level does not cover the cost of the vaccine and a $2.00 injection fee.

As explained by the Blue Cross and Blue Shield Association:

> "Medicare law (Section 1833(a)(1) of the Social Security Act) requires payment to be on the basis of 100% of 'reasonable charges.' Under Medicare law, 'reasonable charges' are calculated in a manner that does not rely solely, if at all, on the costs of the item or service. Reasonable charges are updated on a periodic basis, and are lagged one year (i.e., based on the previous year's distribution of actual charges). Because of the time lag used in this methodology, 'reasonable charges' for medical services often are less than actual charges."

The average nationwide level of Medicare payment for pneumococcal vaccination has not been calculated, and the relationship between payment level and physicians' use of the vaccine has not been measured.

D. Physicians' and Consumers' Perceived Value of Preventing Versus Treating Pneumococcal Disease

1. Physicians' Perceptions and Actions

Data from one study of generalist physicians demonstrates a positive physician attitude toward the use of pneumococcal vaccine, especially among older patients. [Berk] In this study, 69

percent of physician respondents believed that persons aged 50 years and over should receive pneumococcal vaccine. Eighty percent felt it should be administered to patients with congestive heart failure, and 90 percent felt the vaccine was valuable for patients with chronic lung disease. Nearly two-thirds of the surveyed physicians recognized pneumococcal bacteremia as a serious risk of death among the elderly.

In spite of these positive attitudes toward pneumococcal vaccination, in practice physicians do not vaccinate as many patients as the U.S. Public Health Service believes need to be vaccinated. Based upon CDC's 1984 U.S. Immunization Survey data, fewer than 10 percent of the targeted high risk population has ever received pneumococcal vaccine, and fewer than 5 percent were vaccinated in 1984. (See Table 1.) Some authors attribute these low vaccination rates in part to an ambivalence among physicians toward the value of preventing pneumonia among the elderly. [Austrian (1981), Berk (1984b)]

Data from IMS America's National Drug and Therapeutic Index (NDTI) indicates that primary care physicians are most apt to recommend or administer pneumococcal vaccine. [U.S. Congress, OTA, 1984] During 1979-83, 54 percent of all pneumococcal vaccine "mentions" (i.e., any mention of the product during a physician-patient contact) occurred among general or family practitioners, 28 percent occurred among internists, and the remaining 18 percent occurred among all other medical specialty groups combined.

Further, NDTI data indicate that during this same period

over 50 percent of all pneumococcal vaccine "mentions" occurred among physicians aged 50-64 years, another 20 percent occurred among physicians aged 40-49 years, and 14 percent occurred in each of two remaining age groups, i.e., 65 years or older and 20-39 years.

To summarize the NDTI data, 83 percent of pneumococcal vaccinations are likely administered by internists, general or family practitioners. Sixty-six percent of pneumococcal vaccinations are ordered by physicians aged 50 years or older, and 86 percent of the vaccine recipients were aged 45 years or older.

Dr. John Ball, Associate Executive Vice President, American College of Physicians, summarizes his views concerning physicians' use of pneumococcal vaccine as follows: [Ball]

> "I continue to be of the view that individual low cost services and preventive services (usually low cost) are provided <u>not</u> because of their payment levels, but because physicians view them as having value and are <u>consciously</u> aware of the service, i.e., that they view pneumococcal vaccine as beneficial and they <u>remember</u> it when they encounter a patient, for some other complaint, who might benefit from the vaccine. For low-cost services, these fctors seem most important: (1) valid information about the benefit from (2) a credible source (3) in a manner that increases and sustains physician awareness (4) covered with reasonable payment and (5) ease of administration. [For pneumococcal vaccine], we now have (1) valid information

from (2) credible sources (ACP, CDC). But so far, (3) awareness levels are not high, (4) payment levels are minimal, and (5) the physician has to do something to get the patient immunized, (e.g., the vaccine is not listed on the printed charge form, so the patient may have to be called into the office, etc.).

2. Consumers' Perceptions and Actions

No published studies have specifically assessed consumers' perception of the value of pneumococcal vaccination.

One study, designed to improve pneumococcal vaccination rates, found that among 243 patients selected for vaccination, only 3 refused to be vaccinated, although some refusals may not have been recorded. [Siebers] These researchers infer from their findings that suboptimal vaccination rates result from errors of omission on the part of providers (rather than patients).

In a review of pneumococcal immunization for the elderly, Fedson states, "Physician rather than patient attitudes may be more important determinants of whether elderly persons will be immunized." [Fedson, 1984b]

E. Active Methods of Promoting Pneumococcal Vaccinations

During the past five years, successful efforts to increase the use of pneumococcal vaccine within a given health care setting have been reported in the public health and medical literature. All of these reports demonstrate that certain organized efforts within a health care institution indeed yield higher immunization

rates. A few of these reports are described below.

1. In the Outpatient Setting

Pneumococcal vaccine manufacturers reported that between 1978 and 1982, approximately 97 percent of vaccine doses were sold to customers, e.g., pharmacies and physicians, outside of hospitals. [IMS] Several studies report successful efforts to increase the use of this vaccine in outpatient settings, mostly outpatient clinics at teaching hospitals.

The strategic value of immunizing high risk patients in an ambulatory care setting was demonstrated by Magnussen and coworkers at St. Mary's Hospital in Rochester, New York. [Magnussen] He found that among 113 patients hospitalized with pneumococcal infection, 104 (92 percent) had a regular source of medical care and made at least one outpatient visit in the previous three years. Further, only 8 percent of these patients had been vaccinated prior to hospitalization. In 85 percent of all patients and in 97 percent of unvaccinated patients, blood isolates yielded pneumococci types found in the 23-valent vaccine. The authors suggest that vaccination of these high risk patients in an ambulatory care setting during the three-year period preceding hospitalization could have helped prevent or at least reduce the occurrence of pneumococcal infection among this study population.

Fedson and his colleagues implemented programs to stimulate the use of pneumococcal and influenza vaccines in the outpatient General Medical Clinic at the University of Chicago over a six-year period. [Fedson (1977, 1983, 1984)] The primary activities used

to stimulate the use of pneumococcal vaccine included attaching immunization forms to selected patients' medical charts and enlisting the help of clinic nurses and secretaries to identify potential vaccine recipients. Initially, these programs resulted in immunization of about 24 percent of high risk patients. Later, however, these efforts led to immunization rates that were estimated to be five to ten times higher than rates in other University of Chicago outpatient clinics without such programs.

A commonly used mechanism to stimulate pneumococcal or influenza vaccination in outpatient clinics is the mailing of a postcard or letter to high risk patients, reminding them to discuss the vaccine with their physicians or simply to ask for it. [Larson (1979, 1982), Anderson, Spruill, Siebers]

In one such study, Spruill reported that a patient reminder led to 474 of 1,593 (30 percent) high risk patients being immunized with pneumococcal vaccine. No confirmed cases of pneumococcal pneumonia occurred among these vaccinated individuals. Control (unvaccinated) groups were not included in this study, although five cases of pneumonia (probably pneumococcal) occurred among observed, unvaccinated patients. The author estimated that the cost of this program (exclusive of salaries) was offset by revenue generated through clinic visit and vaccination fees. Potential cost savings to the sponsoring health care institution over a five-year period were estimated to be ten times the program's costs.

Letters have also been sent to physicians, successfully reminding them to vaccinate their high risk patients. In one such

program, pneumococcal immunization rates jumped from less than five percent to more than 80 percent. [Gelfman]

Rodney and coworkers at the University of California/Los Angeles demonstrated that the format and position of immunization information in the patient's medical record can influence immunization rates. [Rodney] By reformatting such information, this investigator was able to increase the pneumococcal vaccination rate from 1.6 percent to 19.8 percent among high risk patients in a family medicine clinic.

2. In the Hospital

A few studies have demonstrated the strategic value of identifying and vaccinating high risk patients in the hospital. [Fedson (1985), Magnussen, Klein (1983), Mufson] Such investigations document that approximately 60 to 70 percent of all study patients hospitalized with serious pneumococcal infections (usually pneumococcal bacteremia) had been hospitalized at least once in the preceding three to five years. Preliminary findings from a population-based study conducted within the Medicare population in the Shenandoah area of Northern Virginia revealed that, in 1982, 52 percent of 1,227 Medicare enrollees discharged from a hospital with pneumonia had been hospitalized at least once in the previous three years. [Fedson (1985)]

Fedson has estimated that hospital-based pneumococcal immunization could reduce hospital admissions for all types of pneumonia by 1.1 to 10.9 percent (depending on the assumptions used). [Fedson (1985)] The estimated degree of reduction is

sensitive to changes in seven variables. (See Table 4.)

Table 4. Estimated Preventive Effect of Hospital-based Pneumococcal Immunization

Assumptions	Case 1 (%)	Case 2 (%)
Pneumonias caused by pneumococcal organisms	25	40
Pneumococcal pneumonias caused by vaccine types (23)	80	90
Patients with pneumococcal pneumonia who are immunocompetent	70	90
Efficacy of pneumococcal vaccine	60	80
Patients with pneumococcal pneumonia with previous hospital care (5 years)	50	67
Discharged patients offered pneumococcal vaccine	50	90
Discharged patients offered vaccine who are immunized	50	70
Reduction in hospital admissions caused by all pneumonias	1.1	10.9

SOURCE: Fedson, D. S., "Improving the Use of Pneumococcal Vaccine Through a Strategy of Hospital-based Immunization: A Review of Its Rationale and Implications." J. Amer. Geriatrics Soc. 33:142-150, 1985

In his analysis of data from the Shenandoah study of Medicare patients, Fedson estimated that, if 30 percent of pneumonias are preventable through pneumococcal immunization, vaccination of 56 persons, aged 65 to 74 years, discharged from a hospital for any condition would prevent one future hospital readmission for pneumococcal pneumonia. [Fedson (1985)] Assuming that between 15 and 30 percent of all pneumonias are most likely preventable through pneumococcal vaccine, Fedson estimated that, in general, for every 50 to 100 persons immunized upon hospital discharge, one readmission with pneumococcal pneumonia would be prevented within the next five years.

In two studies, Klein demonstrated how specific interventions can increase pneumococcal vaccination rates among hospitalized patients. [Klein (1983), Klein (1984)] A 1983 study involved 600 hospitalized patients who had at least one medical condition that increased their risk of contracting pneumococcal pneumonia. Such patients were identified upon hospital admission, and none had been vaccinated prior to their hospitalization. Two vaccination-promotion techniques were used, i.e., each patient's hospital chart was stamped to identify them as vaccination candidates, and posters advocating pneumococcal vaccination for high-risk patients were placed in all medical wards. These efforts led to vaccination of about 20 percent of all hospitalized vaccine candidates. Only two percent of a corresponding control group of patients were vaccinated. In a more recent study involving 258 patients, Klein studied the impact of another vaccination promotion technique. [Klein (unpublished)] In an experimental group of 90 high-risk hospitalized patients, an infection control nurse offered to vaccinate against pneumococcal disease. Among 97 control high-risk patients, no such offer was made. In this study, seventy-eight (78) percent of the experimental patients were vaccinated, whereas none of the control patients were vaccinated.

F. Summary

Pneumococcal vaccination rates within a given population are determined by a myriad of factors. Many indirect or passive factors such as physicians' and patients' perceptions about the value of preventing versus treating pneumococcal infections,

attitudes about the vaccine's safety and efficacy, vaccine costs, and reimbursement policies are certainly important. To date, however, based on existing published studies, it appears that active, institutional-based campaigns to promote pneumococcal vaccination of high risk patients have the greatest documented impact on vaccination rates.

The potential impacts of various health care financing mechanisms on the use of pneumococcal vaccine are addressed in the next section of this paper.

IV. IMPLICATIONS OF ALTERNATIVE PAYMENT MECHANISMS ON THE USE OF PNEUMOCOCCAL VACCINE

It is difficult to demonstrate that Medicare reimbursement, by itself, has affected pneumococcal vaccination rates among persons aged 65 years and older. Such an effect would likely have occurred by now--four years after Medicare began paying for pneumococcal vaccination. Annual sales data do not indicate that vaccine utilization is growing. (See Table 3.) Although data from the 1984 U.S. Immunization Survey indicate that perhaps twice as many doses were administered than were sold in 1984, the lack of such data in previous years makes it impossible to assess trends using this source of information.

Several factors could negate or at least diminish a positive relationship between Medicare reimbursement and pneumococcal vaccination rates, e.g.:

(1) Factors other than reimbursement have a greater influence on physicians' supply of and patients' demand for pneumococcal vaccination.

(2) The cost of pneumococcal vaccination is relatively low compared to other medical goods and services, and reimbursement may not be a factor in its utilization rate.

(3) Medicare carriers may reimburse at a level too low to enable providers to cover their vaccination costs or to make a profit.

Based on information cited above, reimbursement may actually be a relatively minor factor in determining the extent to

which pneumococcal vaccine is used. Physicians', and possibly patients', perceptions about the vaccine's "health value," safety, and efficacy may be more important. Notwithstanding this possibility, the nature of the vaccination payment mechanism could influence the vaccine's use to some degree. The possible impacts of alternative payment schemes are described below.

A. Current Medicare Payment Mechanism

As described above, Medicare currently pays for pneumococcal vaccinations through its Part B program, regardless of where the vaccine is actually administered--inpatient or outpatient settings. These vaccinations are not subject to patient deductible or coinsurance requirements or to Medicare's DRG-based hospital payment regulations. One hundred percent of the reasonable (or allowable) charge is paid for by the Medicare program on a fee-for-service basis, with each Medicare Part B carrier determining payment level.

In essence, Medicare has assumed most of the financial responsibility for the use of this vaccine, a situation which removes some, if not most, of the financial barrier to a patient's access to this vaccine (except perhaps transportation costs, copayment for a physician's office visit, and any portion of a vaccination charge that exceeds a carrier's reasonable charge level).

The extent to which a physician recommends or administers this vaccine to Medicare beneficiaries might be influenced by three economic considerations, in addition to his or her percep-

tions about the vaccine's clinical value for a given patient, i.e.,

(1) The degree to which Medicare's vaccination payment level covers the cost of purchasing and administering pneumococcal vaccine, and

(2) The physician's knowledge or perception of the economic value (i.e., cost-effectiveness) of preventing pneumococcal illnesses (primarily pneumonia) among Medicare beneficiaries (of particular importance to physicians treating Medicare beneficiaries on a capitated basis, i.e., in HMOs).

In the following discussion, the possible impacts of selected alternative payment mechanisms on the use of pneumococcal vaccine are discussed.

B. Alternative Payment Methods

1. Modification/Refinement of Current Payment Methods

Background: At present, each Medicare Part B carrier establishes its own payment level for this procedure, and the level varies from carrier to carrier. A small survey of four carriers yielded a range of payment levels from $7.00 to $11.10. Manufacturers of this vaccine charge their private sector, non-hospital customers from $5.30 to $6.80 per dose. Physicians may pay pharmacies an additional 10 percent handling charge, bringing their costs up to about $5.80 to $7.50 per dose. In the region served by the carrier who pays physicians $7.00 to cover a pneumococcal vaccination ($5.00 for the vaccine and $2.00 for

administration), office- or clinic-based physicians most likely pay more than $5.00--and possibly more than $7.00--for the vaccine alone. Hospitals that purchase large quantities of a pharmaceutical product can sometimes negotiate lower prices with manufacturers.

To some extent, a pneumococcal vaccination payment level at or below the cost of rendering that service (including product costs) could be a disincentive for private practice, for-profit physicians to recommend or administer this vaccine. Since this vaccination service is a relatively low cost, low margin procedure, however, a reimbursement level at or near the cost of rendering the service may have a neutral impact on the vaccine's rate of use. It is not likely that many physicians view pneumococcal vaccination as a "profit center" in their practice.

Options: Two options are offered here. First, since Medicare has reduced patients' financial barriers to pneumococcal vaccines (by waiving deductible and copayment requirements), the program might want to help ensure that economic barriers, such as low reimbursement levels, are not hindering physicians' supply of this procedure. If deemed appropriate, such an assessment by Medicare would involve three steps:

(1) Conduct a nationwide survey of carriers' payment levels for the pneumococcal vaccination procedure.

(2) Assess the degree to which these payment levels cover the product and administration costs incurred by physicians who give the vaccine, and

(3) Quantify the relationship (if any) between Medicare's payment level and the degree of use of this vaccine.

If needed, Medicare could act in accordance with the results of this investigation. The two basic options would be:

(1) Do nothing, if payment levels were found to be either adequate (high enough to cover all costs) or inconsequential (have no impact on physicians' use), or

(2) Encourage/require carriers to ensure that their payment levels were high enough to cover costs and not serve as a disincentive to physicians' use of the vaccine.

The Blue Cross and Blue Shield Association, however, claims that basing payment on costs could create inappropriate financial incentives and serious administrative difficulties. [Lehnhard, Sept. 6, 1985] The Association states:

"It could lead to excessive mark-ups of the vaccine itself and to unnecessary vaccinations. It also would appear to require carriers to determine the 'costs' of administering the injection. Physicians currently are not subject to Medicare cost allocation methods and audits, and might well object to such procedures. Carriers would incur major expenses for these tasks. Physicians' office overhead costs, allocated to the vaccination, could substantially increase payments. Finally, payment of costs, even if accurately determined, would move in a direction opposite of recent and proposed Medicare payment reforms for other types of care."

Second, HCFA could promote the use of pneumococcal vaccine among hospitalized Medicare beneficiaries.

As stated by Fedson, approximately two-thirds of Medicare patients destined to develop serious pneumococcal infections have been discharged from a hospital within the previous five years. [Fedson, 1984b] Thus, hospital-based immunizations could help reduce future hospitalizations for pneumococcal pneumonia. As stated earlier, Fedson has calculated that for every 50 to 100 hospital-based immunizations, Medicare could prevent one future admission. [Fedson, 1985]

Medicare could promote hospital-based pneumococcal vaccinations in two ways:

a. Supplying educational materials--including information about clinical need, target population, vaccine safety and efficacy, the economics of preventing pneumococcal pneumonia, and techniques or programs used to deliver the vaccine in a cost-effective manner, e.g., Klein's work.

b. Providing financial incentives--the most obvious of which would be to link payment for the vbaccination to a hospital's DRG payment schedule. The legal and administrative aspects of this method would need to be examined.

Alternatively, HCFA could simply remind hospitals that Medicare reimburses separately for pneumococcal vaccinations (under Part B) and illustrate how to submit claims.

2. Fee Schedules

Background: In essence, each Medicare carrier establishes

its own fee schedule for pneumococcal vaccination. As discussed above, this process results in a wide variety of payment levels. Although charges for many medical procedures, such as vaccinations, vary notably among geographical regions, the manufacturers' price of the vaccine does not vary by geographic region.

Option: If deemed appropriate, Medicare could establish a regional or national fee schedule for this procedure. Such a process would be similar to that being developed and implemented by Medicare for clinical laboratory tests. The impact of doing so again would likely depend on the payment level established and the relationship between this level and use. The administrative costs of establishing such a fee schedule would need to be considered.

3. Packaging/Bundling

Background: In recent Congressional testimony, Dr. Robert Kane, Senior Researcher, The Rand Corporation, suggested that Medicare could make "a special bonus payment to physicians who agreed to assume primary care responsibilities for a Medicare beneficiary, including a special battery of preventive practices." [Kane] Dr. Kane further suggests that payment for such a package could be around $100 (the average fee for a comprehensive office visit) and be subjected to a 20 percent patient copayment requirement. Conceivably such a package could include pneumococcal vaccination.

Separate payments for preventive services is a relatively new idea for health insurance programs. Traditionally, insurance policies are designed to pay for services related to the diagnosis

and treatment--not prevention--of illnesses. As stated in recent Congressional testimony by Mary Nell Lehnhard, Vice-President, The Blue Cross and Blue Shield Association, "This practice [not paying for disease prevention services] is consistent with the basic principle of insurance which is to spread risks that are unpredictable and difficult for the individual to bear. For insurance purposes, preventive services are regarded as a limited, predictable, budgetable expense, and consequently, not appropriate for coverage." [Lehnhard] Ms. Lehnhard also stated that in Blue Cross/Blue Shield's experience, employers are unwilling to provide such (preventive) benefits, because "there is no assurance that, even if the services are cost-effective in the long run, the savings will accrue to the employer who is currently financing the preventive services." While this situation is true for employers, Medicare would likely reap the benefits, whatever they may be, as well as the costs of paying for preventive services, because Medicare continues to pay for beneficiaries' health care for the duration of their lives.

While recognizing that health insurance coverage traditionally excludes payment for preventive services, Mr. James R. Brennan, Vice President, Group Marketing, Northwestern National Life Insurance Company, claims this situation is changing. Again in recent Congressional testimony, he stated, "We see this changing as preventive care more and more comes to be viewed as a cost containment measure or as a trade-off against other types of coverage. A survey conducted in 1983 by the health and life

insurance industry's Center for Corporate Public Involvement revealed that out of 147 responding insurance companies, some 36 companies made preventive care benefits available to group policyholders. Most frequently, these were well baby care benefits, but also included physical examinations, vision care, dental care, immunizations, and health risk and stress appraisals." [Brennan]

Option: This option would entail including pneumococcal vaccine in a package of services, perhaps preventive in nature, that would be offered to each Medicare enrollee. Such a service package could be delivered to each new Social Security recipient upon his or her enrollment in the Medicare program. Current enrollees could receive the package within a designated time period subsequent to enactment of a provision authorizing/requiring such a package.

A key determinant to the development of this option is the insurer's, e.g. Medicare, perception regarding the economic and health "rate of return" on investing in health promotion and disease prevention services. To the extent that data can illustrate the degree to which such investments are "cost-effective," then this packaging approach may make sense, especially since Medicare pays a major portion of its beneficiaries' health care bills until death. For those service packages found to be cost-effective, Medicare could adjust its payment level in accordance with the degree of returned benefits.

HCFA, through its Office of Demonstrations, recently awarded two grants, one to the University of North Carolina (UNC)

and one to Blue Cross of Massachusetts (BCM), to provide a set package of preventive services to Medicare fee-for-service enrollees. In these two programs, such packages will be rendered annually for six years and include selected clinical services, e.g., breast examination, digital rectal exam, hearing exam, high blood pressure screening, cervical cancer screening, height and weight measurements, hematocrit, history and physical, stool occult blood test, vision, and influenza vaccination. These packages also include certain health promotion/educational services, e.g., risk reduction, medication awareness, smoking cessation, physical exercise, nutritional and mental hygiene education, and others. HCFA will pay participating providers $100 per year to deliver their packages. The impact of the preventive packages on the incidence, prevalence, and cost of selected illnesses, e.g., colon cancer, high blood pressure, and influenza, will be measured. In both projects, enrollees can volunteer to receive the package. In the UNC project, enrollees will receive the services from their regular source of medical care, whereas in the BCM project, enrollees will go through a special selection process and to a special clinic.

Influenza vaccination is included in both grantees' packages of services. Pneumococcal vccination is not included in either pcakage, because Medicare already reimburses for this benefit. Perhaps, however, by monitoring the clinical and economic impacts of influenza vaccinations in these two projects, Medicare can better estimate the value of pneumococcal vaccination among its enrollees.

4. Capitation

Background: Theoretically, HMOs have financial incentives to render preventive services to their enrollees, i.e., the healthier the enrolled population, the lower the use of expensive treatment services, e.g. hospitalization. Further, the relatively low cost of this procedure compared to other services should not represent a major financial barrier to its use in HMOs.

Those HMOs that contract with Medicare are already legally required to provide all Part A and Part B service and can offer additional benefits. According to a 1984 government report, experience suggests that HMOs and CMPs (Competitive Medical Plans) participating on a risk-contracting basis may voluntarily offer some preventive health services to their Medicare enrollees, including vision and hearing screenings, periodic physical examinations, and immunizations. [U.S. Dept. of HHS, 1984]

The degree to which HMOs and CMPs provide preventive services, as compared to fee-for-service settings, has not been quantified. [U.S. Congress, OTA, 1982]

There are, however, a few studies. An almost universal finding has been that enrollees in prepaid groups and, to a lesser extent, IPAs have higher rates of visits classified as preventive than comparison groups. [Luft] Part of this difference may stem from the tendency of HMO enrollees to be more oriented to prevention. One analyst attributed the higher rate of preventive visits to the more complete benefit coverage of ambulatory and preventive services rather than to the effect of HMOs themselves. [Luft]

This generalization did not apply to the comparison of a multispecialty fee-for-service group in Palo Alto and a Kaiser-Permanente plan. [Scitovsky] The Palo Alto Medical Clinic had significantly higher annual rates of Pap smears (47 percent versus 34 percent of women) and general preventive visits, with the greater use connected with having a regular physician. Although the clinic rate is noteworthy because patients paid a 25 percent coinsurance rate, the clinic also had more women from higher socioeconomic groups, who are more likely to have Pap smears.

There have been too few studies of immunization rates to draw general conclusions. In two (of three) studies, children in prepaid groups had higher immunization rates than controls in fee-for-service solo practices. [Luft] No pattern was evident among Medicaid eligibles with comparable coverage. Children in a Washington, D.C. prepaid group had significantly lower immunization rates, although that study had design problems. [Beck, Fuller] A larger study of Medicaid eligibles found little difference or slightly lower rates in prepaid groups and IPAs compared with fee-for-service controls. [Gaus] These two studies reported similar findings for prenatal care--lower or equal use in prepaid groups. The poor in Seattle prepaid group had higher immunization rates, except for influenza vaccine. [Luft]

Even though current laws and regulations require HMOs under contract with Medicare to make all Part B services available, the decision to vaccinate a Medicare enrollee against pneumococcal disease still rests with the enrollee's physician, and/or an HMO's

policy decisionmakers, not with Medicare. This decision is subject to all the factors discussed in previous sections of this report, e.g., perceived need for the vaccination, etc.

Dowd has described a theoretical financial analysis that HMOs can undertake to help assess the economic impacts of providing preventive health services. [Dowd] He identified three potential benefits that accrue from preventive health measures:

(1) financial benefits to the HMO in the form of reduced expected medical expenditures,

(2) perceived personal benefits to the subscriber from the reduced risk of encountering accidents or illness, and

(3) possibly, benefits to society from optimal investment strategies.

To help HMOs calculate the benefits of primary prevention interventions, e.g., vaccinations, Dowd advocates estimating the reduced probability of an individual encountering an accident or illness (as a result of the intervention) and calculating the expected value of medical expenses incurred before and after the preventive service is used. By computing such expected values, HMOs can compare the cost of implementing a prevention measure with the potential resultant savings.

According to Dowd, the costs and benefits of primary prevention for both the HMO's and the enrollee's perspective depend on four factors:

(1) the reliability of probability estimates of illness occurring at particular points in time,

(2) the reliability of probability estimates of the effectiveness of the prevention measure,

(3) the cost of the measure, and

(4) the individual's or HMO's attitude toward risk.

Calculating accurate probability estimates can be difficult for many prevention interventions, because dependable data are not always available. As a result, HMOs and their enrollees can be forced to use more subjective evaluations to calculate potential costs and benefits.

Dowd identified two types of HMO costs associated with implementing a prevention program:

(1) the direct costs of purchasing educational materials and medical supplies needed to render the selected service(s), and

(2) the indirect costs associated with the uncertainty of subscriber enrollment in the HMO.

(NOTE: As mentioned below, thus far, Medicare beneficiaries who enroll in HMOs appear to stay with their chosen plans.)

Calculating the expected value of a preventive measure from the enrollee's perspective is usually more difficult than calculating the HMO's financial benefits. The primary reason for this situation is that such a quantification requires knowledge about the value the enrollee assigns to the avoidance of a particular illness.

Dowd advocates that society as a whole benefits from prevention efforts which prove to be good investments. He contends

that since governments (federal, state, and local) finance a substantial portion of the nation's health care bill, the public sector may have a limited role in financing preventive measures. He suggests three possible roles:

(1) Encouraging the development of standard protocols for administering prevention programs and certifying programs;

(2) Informing HMOs and enrollees of the alternative methods of sharing the risks of prevention; and

(3) Funding research to improve the reliability of probability estimates of both the occurrence of illness and effectiveness programs.

There are at least four factors that are likely to influence an HMO's enthusiasm for administering pneumococcal vaccine. The first factor is vaccination costs, which are relatively low. The second factor is the perceived cost-effectiveness of pneumococcal vaccination compared to the traditional approach of treating pneumococcal diseases once they occur. Third, to some degree, HMO-participating physicians may possess a traditional, less than enthusiastic attitude about the value of preventive services in general and pneumococcal vaccination in particular. And the fourth factor is the "turn-over" rate among Medicare beneficiaries within a given HMO or CMP.

Experience with turnover rates among Medicare enrollees in HMOs is new and hence data are limited. Information from HCFA's HMO Medicare demonstration projects, however, indicate that in

1984 HMO disenrollment rates (for all causes, including death) among 12,000 Medicare beneficiaries averaged about 9.4 percent. [Langwell] Other sources verify that such disenrollment rates are indeed quite low. [Fowler, Pickins] This relatively low rate contrasts with higher rates reported previously among other populations. A 1979 report from the Southern California Region of the Kaiser-Permanente Medical Care Program claimed that a large HMO experienced a 15 to 20 percent annual turnover in enrollee membership. [Hester] In another study, disenrollment within the Medical Care Group of St. Louis, an HMO serving 25,000 enrollees was 33 percent. [Boxerman and Hennelly] Disenrollment rates among HMOs with a high proportion of Medicaid members have been reported earlier as high as 66 percent. [D'Onofrio and Mullen] In this particular Medicaid study, however, about two-thirds of this turnover was due to loss of Medicaid eligibility; the remainder was attributed to deliberate resignations.

Because of the tremendous rate of growth in HMO development, however, disenrollment rates for Medicare beneficiaries should be compared with <u>contemporary</u> disenrollment rates among other populations, e.g. employed and Medicaid. Many changes that could affect disenrollment, e.g., scope and location of services offered, have occurred among HMOs since these previous studies were performed.

<u>Option(s)</u>: Medicare could take one or both of the two following options related to the use of pneumococcal vaccine in HMOs:

(1) Study the economic and clinical impacts of pneumococcal vaccination among Medicare HMO enrollees, and/or

(2) Promote the vaccine's use by--

a. Supplying to HMOs (who accept Medicare enrollees) information and educational materials about the economic and clinical effects of pneumococcal vaccinations.

b. Giving HMOs financial incentives to administer pneumococcal vaccine to Medicare enrollees.

Option 1: Medicare could finance a multi-site demonstration project in which the financial implications of this procedure are quantified. Such a study could generate data necessary to perform the assessments described by Dowd. (See above.) Since several HMOs now provide care to Medicare beneficiaries on a capitated basis, identification of good study sites should not be difficult.

Alternatively, Medicare could add this procedure to the package of preventive services soon to be studied by HCFA's Office of Research and Demonstrations. Although these services will be rendered on a fee-for-service basis, the clinical and some economic impacts of the vaccine could be extrapolated to an HMO setting. Differences in the providers' financial incentives would need to be considered.

Option 2: In order to actively promote the use of this vaccine, Medicare would have to be convinced that the economic and health value of this procedure exceeded its costs.

(a) HCFA, in conjunction with the Public Health Ser-

vice, could develop educational materials that explained several aspects of pneumococcal vaccination to participating HMOs. Topics to be covered could include these:

- Clinical need and target populations
- Vaccine safety and efficacy
- Cost-effectiveness data
- Suggested vaccination programs and procedures

Materials for patients as well as providers and administrators could be developed.

(b) HCFA could give HMOs financial incentives to provide pneumococcal vaccinations by paying a separate fee for vaccination services (which might include influenza and other vaccinations).

Creating special incentives or mandatory vaccinations exclusively within HMOs does not seem appropriate, because if vaccination is deemed beneficial, it should be promoted equally among all Medicare enrollees, including the vast majority who receive health care on a fee-for-service basis.

Further, special payments for any service within HMOs is contrary to the philosophy and operations of HMOs.

In order to actively promote the use of this vaccine, however, Medicare would have to be convinced that the economic and health value of this procedure exceeded its costs.

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